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EXAMINER	
PORTNER, VIRGINIA ALLEN	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 08/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/904,994	KUSTERS ET AL.	
	Examiner	Art Unit	
	Ginny Portner	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 April 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23,26,28,30-34,37-40,44,46-50 and 57-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23,26,28, 30-34,37-40,44,46-50 and 57-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Amended Claims 23, 26,2 8, 30-34, 37-40, 44, 46-50, 57-59 are pending.
Claims 1-22, 24-25, 27, 29, 35-36, 41-43, 45, 51-56 have been canceled.

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Rejections over canceled claims are automatically withdrawn.

Objections/Rejections Withdrawn

1. ***Objections Withdrawn***: The objection to claims 37-39 to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is traversed on the grounds that the dependent claims must include all of the limitations of the independent claim and therefore are further limiting has been obviated through amendment of the claims to recite a minimum size and a combination of limitations that evidences a higher degree of homology, and is therefore further limiting.

2. ***Objections Withdrawn***: The objection to claim 44 under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is traversed on the grounds that the dependent claims must include all of the limitations of the independent claim and therefore are further limiting has been obviated through amendment of the claims to recite a minimum size and a combination of limitations that evidences a higher degree of homology, and is therefore further limiting.

3. ***Rejection Withdrawn,*** 35 U.S.C. 112, second paragraph: The rejection of claims 23, 26, 28, 30-34, 37-40, 44, 46-50, 57-58 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reciting the term "homologous" or homology, in light of the amendment of the claims to recite the specific parameters shown to determine the % homology set forth in Applicant's Specification.

4. ***Claim Rejections - 35 USC § 112 Withdrawn:*** Claim 39 rejected for reciting the limitation "The polypeptide of claim 31" in an effort to further limit claim 31, but claim 31 is directed to a DNA sequence has been obviated by amending claim 39 to depend from claim 34.

5. ***Claim Rejections - 35 USC § 101*** Claims 23, 26 and 28 rejected under 35 USC 101 for not being directed to isolated and purified nucleic acid molecules has been obviated by amending the claims to recite ------isolated and purified-----.

Response to Arguments for Objections/Rejections Maintained

6. Applicant's arguments filed 25 April 2006 have been fully considered but they are not persuasive.

7. ***Claim Rejections - 35 USC § 112 Maintained (gene therapy, nucleic acid immunization compositions):***

The rejection of claims 46-49 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the *invention is traversed* on the grounds that:

"The enablement rejection of the claims is improper because they have been examined in light of gene therapy art, which is irrelevant to the claimed subject matter" and asserts that the instantly claimed compositions of claims 46-49 "pertain simply to immunogenic compositions".

8. It is the position of the examiner that the nucleic acid molecules contained in the compositions of claims 46-49 would not induce an immune response to Helicobacter felis polypeptide, the coding sequence of SEQ ID NO 1, absent specific regulatory sequences being in association with SEQ ID NO 1, so it would not only be transcribed, but translated and secreted so an immune response could be generated. The term gene therapy is a broad term that encompasses replacement of defective genes, but also includes DNA vaccines that will transform a eukaryotic cell in a mammal which in turn will express the heterologous nucleic acid. Baird et al (2004) utilized Ig signal sequence together with epitopes to insure secretion by a mammalian cell. The instantly claimed compositions do not comprise any of the critical components to insure induction of an immune response to Helicobacter felis urease polypeptide. The claims now pending are directed to bacterial nucleic acid sequences that in and of themselves would not induce an immune response that is specific to Helicobacter felis urease based upon any of the nucleic acid sequences being directly administered to the blood stream of an animal and the claims do not recite any structural regulatory elements to insure the induction of an immune response if and when the nucleic aid molecule were taken up by the appropriate eukaryotic cell to insure the encoded polypeptide is expressed to induce an immune response. Numerous factors complicate the gene therapy art which have not been shown to be overcome by routine experimentation. These include, the fate of the DNA vector itself (volume of distribution, rate of clearance into the tissues, etc.), the *in vivo* consequences of altered gene expression and protein function, the fraction of vector taken up by the target cell population, the trafficking of the

genetic material within cellular organelles, the rate of degradation of the DNA, the level of mRNA produced, the stability of the mRNA produced, the amount and stability of the protein produced, and the protein's compartmentalization within the cell, or its secretory fate, once produced. These factors differ dramatically based on the vector used, the protein being produced, and the disease being treated. With respect to claim 48, it was noted that HIV viral epitopes are defined within the scope of the claim to induce an immune response to HIV and to serve as a vaccine (instant Specification, page 7, paragraph 1). Bourinbaiar et al (2006) states that proposed vaccines for HIV "have shown little evidence of clinical efficacy (see abstract)." No known HIV vaccines are known "as a result of vaccination, the clinical improvement has been seldom observed."

9. While the instant Specification does provide guidance for the construction of recombinant host cells that recombinantly/heterologous express the encoded H. felis nucleic acid (see instant Specification page 4, lines 28-49 and page 5, lines 6-21), what is now claimed is an immunogenic composition that comprises the coding sequence for H.felis polypeptide, a prokaryotic coding sequence which does not naturally comprise the necessary promoters, polyA, and other regulatory sequences to successfully have the bacterial nucleic acid translated into a polypeptide and secreted into the immunocompetant host animal and to serve as a DNA vaccine/immunogenic composition. Permin et al (2005, page 21, col.1, p. 1) teaches that "genetic difference in the individual immune responses to the pathogen, for example linked to IL-1 gene cluster polymorphism, may result in failure to eradicate the infection and lead to chronic mucosal inflammation

Therefore, even if the specification is enabled the construction of the gene delivery vehicle comprising a cell targeting element, in the absence of particular guidance, the artisan would have been required to develop *in vivo* and *ex vivo* means of practicing the claimed methods and such development in the nascent and unpredictable gene/vaccine therapy art would have been considered to have necessitated undue experimentation on the part of the practitioner.

With respect to the cited references:

- Hasan et al (Exhibit A) summarized various vector mediated delivery systems for expression of a heterologous immunogen, and describes various promoters, plasmids, viral vectors, bacterial vectors for delivery of foreign encoded nucleic acids; Applicant's claims are directed to only a nucleic acid molecule and is not in association with a promoter, plasmid or vector construct as described by Hasan. The term "naked DNA" in Hasan is a plasmid that encodes a heterologous coding sequence (see page 3, section 2), as compared with the coding sequence being inserted into a viral vector (see page 7, section 3.1.1, Hasan et al) or attenuated bacterial vectors (see Hasan et al, page 7, section 3.2). Exhibit A does not present evidence commensurate in scope with the instantly claimed invention as now claimed.
- Todoroki et al (2000) utilized a plasmid to express the coding sequence for H.pylori; the compositions of instant claims 46-49 do not comprise an eukaryotic promoter, plasmid, viral vector or attenuated bacteria for the expression H. felis urease. Exhibit B does not present evidence commensurate in scope with the instantly claimed invention as now claimed.
- Miyashita et al (2002) utilized a plasmid to express the coding sequence for H.pylori; the compositions of instant claims 46-49 do not comprise an eukaryotic promoter, plasmid, viral vector or attenuated bacteria for the expression H. felis urease. Exhibit C does not present evidence commensurate in scope with the instantly claimed invention as now claimed.
- Hatzifoti et al (2004) utilized a plasmid to express the coding sequence for H.pylori; the compositions of instant claims 46-49 do not comprise an eukaryotic promoter, plasmid, viral vector or attenuated bacteria for the expression H. felis urease. Exhibit D does not present evidence commensurate in scope with the instantly claimed invention as now claimed.

The rejection under 35 USC 112, first paragraph, over claims directed to and encompassing DNA vaccines/gene therapy is maintained for reasons of record, and responses set forth herein.

10. ***Claim Rejections - 35 USC § 102 Maintained***: The rejection of claims 23, 26, 28, 30-34, 37-40, 44, 46-50, 57-59 under 35 U.S.C. 102(b) as being anticipated by Labigne et al (US Patent 5,843,460) is traversed on the grounds that the claim amendments over come the applied prior art in light of the claim amendments that now recite "determined over a global alignment".

11. It is the position of the examiner that amended claims 23, 26, 28,30, and 46-48 are still anticipated by Labigne et al's disclosure because the claimed isolated nucleic acid molecule must comprise a nucleotide sequence that encodes a polypeptide of urease X and Y (ie claim 23, subparagraph a) X or Y (ie claim 23, subparagraph b), the size of the claimed nucleic acid not being required to be any specified size, but this nucleic acid has to share at least 85% homology with SEQ ID No 1, but does not have to be the same size as SEQ ID NO 1, but only share 85% homology over the nucleotides that make up the shared portion of the claimed nucleic acid molecule. The claimed nucleic acid must comprise an range of nucleic acids that shares

a. a part of the SEQ Id NO 1, or the nucleic acid of at least 85% homology of SEQ ID NO 1, the part encoding an immunogenic fragment, the fragment being at least 70 nucleotides in length. (X being an identical nucleic acid; - - - being unidentical)

Apart of Reference sequence SEQ 1: XXXXXXXXXXXXXXXXXXXX----------

Prior art sequence: XXXX - -XXXXXXXXXX – XXX----------

Immunogenic epitopes are usually 3-10 amino acids in length, thus a nucleotide sequence of 9 to 30 nucleotides would define an immunogenic portion of the part of 70 nucleotides would need to be identical to SEQ ID NO 1, or evidence a sequence that defines the immunogenic part claimed.

- Labigne et al discloses SEQ ID NO 19, which is a nucleic acid sequence of 2619 nucleotides in length, and thus is a nucleic acid that comprise a part of SEQ Id NO 1 which has 2883 nucleotides in the sequence. SEQ ID NO 19 of Labigne et al encodes a Helicobacter homologous polypeptide which shares 100% sequence identity in a number of regions of SEQ ID NO 1, which encode immunogenic parts of SEQ ID NO 1. The nucleic acid of Labigne et al encoding at least an immunogenic fragment of one of the subunit polypeptides that would induce an immune response that would immunoreact with SEQ ID NO 1. SEQ ID No 19, shares 100% sequence identity with nucleic acids 1134-1160 of SEQ ID NO 1, as well as encodes a functional

homolog of the instantly claimed Helicobacter felis urease. Labigne et al still anticipates the instantly claimed invention as now claimed.

- Labigne et al's sequence SEQ Id NO 23 is a 100 amino acid polypeptide encoded by a nucleic acid molecule. The nucleic acid molecule defined by the amino acid sequence shows a nucleic coding sequence that shares 100% sequence identity over a number of regions which could induce an immune response, the nucleic acid that would encode a 100 amino acid sequence would be about 300 nucleotides and thus is a nucleic acid molecule that comprises more than 70 nucleotides. The parts of SEQ ID NO 1 that comprises a part thereof is within the region of nucleotides 206 to 505 of SEQ Id NO 1.

1. The scope of claims 34, 37-38 and 57 include directed to:

* polypeptides that comprise an amino acid sequence that is at least 85% homology to SEQ ID NO 2,

* immunogenic fragments that comprise 70 amino acids, and will induces an immune response to urease X.

- Labigne et al's coding sequence of SEQ ID NO 19, encodes a polypeptide fragment of SEQ Id NO 2 and shares "an amino acid sequence that is at least 85% homologous to SEQ ID NO 2", and would induce an immune response to urease X (see sequence alignment provided).
- Labigne et al's sequence SEQ ID NO 23 is a polypeptide of 100 amino acids, and comprises an amino acid sequence with at least 85% homology with SEQ ID NO 2, wherein the amino acid sequence of Labigne et al shares 100% identity over at least four amino acid sequences that share 100% identity with SEQ ID NO 2.

2. Claims 40, 44 and new claim 58 are directed to polypeptides and immunogenic compositions that comprise the polypeptides of:

- SEQ Id No 3,

- A polypeptide that comprises an amino acid sequence that is at least 85% homologous with SEQ ID NO 3;
- an immunogenic fragment that is at least 70 amino acids in length and induce an immune response to urease Y.

Labigne et al disclose a nucleic acid that encodes a polypeptide that comprises an amino acid sequence for SEQ ID NO 3 (amino acid sequence). Labigne et al SEQ ID NO 19 shares over 2200 nucleotides in common and codes for an amino acid sequence of SEQ ID NO 3 that shares at least 85% homology with "an amino acid sequence of SEQ ID NO 3", wherein the polypeptide encoded by SEQ ID NO 19, shares multiples amino acid sequences which are 100% identical to SEQ ID NO 3.

While Labigne et al does not refer to the Helicobacter felis urease which comprises two subunits, as urease subunit X and Y, the disclosed Helicobacter felis urease subunits of Labigne et al anticipate the instantly claimed invention directed to Helicobacter felis urease homologs that share a nucleic acid sequence with at least 85, 90, 94 or 97 % sequence homology with SEQ ID NO 1.

(Instant claims 31-33, 46-48) Labigne et al disclose a recombinant DNA molecule comprising a nucleotides sequence according to claim 23 under the control of a functionally linked promoter (see col. 13, lines 30-37). The recombinant DNA is incorporated into a live recombinant carrier, which includes viruses, baculovirus, vaccinia viruses, and transformation vectors (see col. 13, lines 44-45). Among the host cells that are transformed with the nucleic acid molecule of claim 23, the DNA fragment of claim 30, the recombinant DNA of claim 31 or the live recombinant carrier of claim 32, include E.coli, Shigellae, Salmonella, Mycobacterium tuberculosis, and eukaryotic host cells (see col. 13, lines 38-51).

(Instant claims 34-39, 53) Labigne et al discloses the instantly claimed Helicobacter felis polypeptide (see Labigne et al, col. 7, lines 15-32) that comprises an immunogenic fragment of

SEQ ID NO 2, wherein the polypeptide is immunogenic and would induce an immune response against ureaseXY, wherein the polypeptide of SEQ ID NO 23 of Labigne et al shares 100% identity over a fragment (Labigne col. 7, lines 29-32) of SEQ ID NO 2 "KTVAQLMEE" AND "TFPDGTKL", and shares 56 identical amino acids with SEQ ID NO 2.

(Instant claims 40-45, 53, 59) Labigne et al also disclose an isolated polypeptide that comprises an immunogenic fragment, wherein the polypeptide is at least 50 amino acids in length and shares at least 97% sequence homology with an amino acid sequence of SEQ ID NO 3 (see sequence alignment with extensive regions that share 100% identity with SEQ ID NO 3).). The polypeptides/proteins are disclosed for a diagnostic test for detection of Helicobacter felis infection (see col. 12, lines 2-5 "in-vitro detection" of antibodies in a sample).

(Instant claims 46-49) Compositions that comprise a pharmaceutically acceptable carrier (see col. 9, lines 15-22; col. 13, lines 52-59) together with a nucleic acid, or immunogenic Helicobacter felis urease homolog, carrier or host cell (see col. 13, lines 30-59) together with an additional antigen HspA or HspB, or homolog thereof (see Labigne et al, col. 31, lines 25-50 and col. 8, lines 33-38, especially col. 31, lines 31-32) "Chlamydia" are disclosed.

Instant claim 50, 54: Compositions of anti-Helicobacter felis urease antibodies are disclosed (cross reactive, see col 9, lines 6-14) for providing passive immunity, and therefore function as vaccine compositions comprising antibodies (see Labigne et al, col. 9, lines 27-30; see col. 10, lines 62-67, col. 11, lines 1-67 and col. 12, lines 1-5). The antibodies are disclosed for a detection of Helicobacter felis urease polypeptides in a sample (see col. 10, lines 64-67 col. 11, lines 1-19 and 20-30). Labigne et al still anticipates the instantly claimed invention.

3. ***Claim Rejections - 35 USC § 112*** Claims 23, 26, 28, 30-34, 37-39, 40, 44, 46-50, 57-59 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is traversed on the grounds that the claims have been amended to clarify the meaning of homology and that parts or fragments must be at least 70 nucleotides or amino acids long.

4. It is the position of the examiner that what parts or regions of SEQ ID NO 1, 2 and 3 that have been chosen to be apart of the claimed nucleic acid and polypeptides has not been described, nor have the recombinant genes used to produce a plurality of protein forms of homologous urease XY, other than those shown in Figure 1a have not been described. While paragraph b) of the claims now requires the size of the product to be at least 70 residues, what portion or portions of the 70 residues encode an immunogen or are immunogenic have not been described. All of the claims are defined by product by process limitations and the gobal alignment now recited, does not require the claimed nucleic acid to be the same size as the reference SEQ ID NO, but to comprise a number of residues that share the recited % homology when compared to the reference SEQ ID NO, but may comprise additional residues/sequences that need not be globally aligned.

5. While specific species defined by specific nucleic acid sequences and complete amino acid sequences shown in Figure 1a have been disclosed, what the claimed nucleic acid molecules and polypeptides are, that only comprise any nucleotide sequence or an amino acid sequence region, a small portion of the sequences recited, and additionally comprise unspecified nucleic acids and amino acids to result in the claimed nucleic acid and polypeptide and that will induce an immune response has not been described..

Applicant also broadly describes the invention as embracing any substitution, insertion or deletion of amino acids throughout the entire stretch of nucleotides or amino acids found in the reference sequence by use of language in which only a "part" or "fragment" of the reference

sequence is required, but the final relative molecular weight of the resultant protein is far larger than the region that can be selected from the reference proteins. None of the proteins that comprise any antigenic region of the recited sequence and reacts with an Helicobacter felis urease antibody, but differs by any number of amino acids, and has a sequence not represented by the sequences of SEQ ID NO 1, 2 or 3 and, encode or comprise amino acid sequences that do not meet the written description provision of 35 USC 112, first paragraph. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.).

The claimed nucleic acids and polypeptides that comprise sequences other than those set forth in Figure 1a, SEQ ID NO 1, 2 or 3, and only comprise an antigenic epitope of 3-10 amino acids out of a possible 700+ amino acids fail to have an adequate written description in the instant specification. The specification does not provide original descriptive support for what the additional amino acid sequences are, that are in association with any number of parts, fragments or regions selected from each of the recited Helicobacter sequences.

The skilled artisan cannot envision all the contemplated nucleic acid molecules or polypeptides/proteins that encode or comprise any amino acid antigenic sequence region of Helicobacter felis ureaseXY. The detailed chemical structure of the claimed genus of proteins has not been described and therefore conception cannot be not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. A method of screening for antigenic immunoreactivity is not a method of making a protein, the product itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481, 1483. . Thus, the written description of the instant specification does not provide for "comprising" language. Therefore, only isolated nucleic acid molecules and polypeptides of SEQ ID Nos 1, 2 and 3 and those shown in Figure 1a have been described but

not the full breadth of the claim meets the written description provision of 35 USC 112, first paragraph. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is serviceable from its enablement provision. (See page 1115.) Applicants are directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999. The rejection is maintained for reasons of record and responses set forth herein.

12. ***Claim Rejections - 35 USC § 102 Maintained.*** The rejection of amended claims 23,26,28,30, 33,34,37-39,40,44,57,58 and new claim 59 under 35 U.S.C. 102(b) as being anticipated by Gootz et al (1994) is traversed on the grounds that:

"Applicants have amended the claims to clarify the meaning of homology. The claims are not restricted to i.) nucleotide or peptide sequences having the requisite homology as defined using the recited algorithmic parameters in an alignment against the entire length of the recited SEQ ID No. (i.e. a global alignment), or ii) a 70 nucleotide or amino acid long stretch of such sequences will also necessarily have the requisite homology as defined using the recited algorithmic parameters. Since Gootz et al. fails to disclose such sequences, Applicant's believe that this rejection is now moot and respectively request the Examiner to reconsider and withdraw the rejection."

13. It is the position of the examiner while the claims have been amended to recite product by process limitations directed to gap lengths and mismatch factors for sequence alignment, Gootz et al produced the claimed and disclosed polypeptide, coding nucleic acid and antibodies by a different process to obtain the same or equivalent products. Gootz et al chose H. felis ATCC 49179 (see abstract), also known as CS-1, the identical strain Applicant used to determine the

sequence for urease as shown in Figure 1(a), SEQ Id NO 1 and isolated and purified the Helicobacter felis urease polypeptide (see Gootz et al, page 794, col. 1, paragraph 5), showed antibody compositions immunoreactive with the polypeptides (see Gootz et al, page 794, col. 2, paragraph 4, and Figure 3, page 795) and isolated the genes for H. felis urease in genomic blots of H.felis ATCC 49179 (see Figure 4), thus isolating the nucleic acid coding sequences for the H. felis urease polypeptides of CS-1.

14. While Gootz et al do not disclose the amino acid sequence, or nucleic acid sequences of the H. felis polypeptide and corresponding coding sequences for the H.felis CS-1 urease, by all comparable data the polypeptide, nucleic acid and antibodies immunoreactive to the polypeptide are the same or equivalent compositions now claimed produced by a different process, but obtained from the identical Helicobacter felis source as Applicants. The amino acid sequence and nucleic acid sequence of a polypeptide and nucleotide molecule, respectively, are descriptors of inherent structural residues of the polypeptide and DNA of Gootz et al. Discovery of a new descriptor of an already known product does not define a novel or unobvious product.

Gootz et al still inherently anticipates the instantly claimed invention. Atlas Powder Co. V IRECA, 51 USPQ2d 1943, (FED Cir. 1999) states Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior arts functioning, does not render the old composition patentably new to the discoverer. The Court further held that Athis same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art.

New Grounds of Rejection

15. Claims 34, 37-38, 50 and 57 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims recite the phrase "at least 85% homologous to SEQ ID NO 2"(claim 34, 50 and 57) , "at least 90% homologous to SEQ ID NO 2" (claim 37), "at least 94% homologous to SEQ ID NO 2 (claim 50). Original descriptive support for the instantly claimed subgenus of species defined by the amended combination of claim limitation; the amended claim limitations could not be found in the instant Specification. Applicant is invited to point out where in the instant Specification that the claimed combination of claim limitations relative to SEQ ID NO 2 can be found. These claims recite New Matter.

Conclusion

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp
August 4, 2006

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600